(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 August 2003 (21.08.2003)

PCT

(10) International Publication Number
WO 03/068111 A1

(51) International Patent Classification[7]: A61F 2/44

(21) International Application Number: PCT/DK03/00081

(22) International Filing Date: 8 February 2003 (08.02.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PA 2002 00217 13 February 2002 (13.02.2002) DK

(71) Applicant *(for all designated States except US)*: **DANFOSS A/S** [DK/DK]; DK-6430 Nordborg (DK).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CHRISTENSEN, John** [DK/DK]; Vestertoften 39, Svenstrup, DK-6430 Nordborg (DK). **PEDERSEN, Hans, Jørgen** [DK/DE]; Benztrasse 2, 71720 Oberstenfeld (DE).

(74) Common Representative: **DANFOSS A/S**; Patent Department, DK-6430 Nordborg (DK).

(81) Designated States *(national)*: AM, AT, AU, BA, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HR, HU, IL, IN, IS, JP, KR, KZ, LT, LU, LV, MD, MK, MX, NO, NZ, PL, PT, RO, RU, SE, SG, SK, TR, UA, US, UZ, VN, YU, ZA.

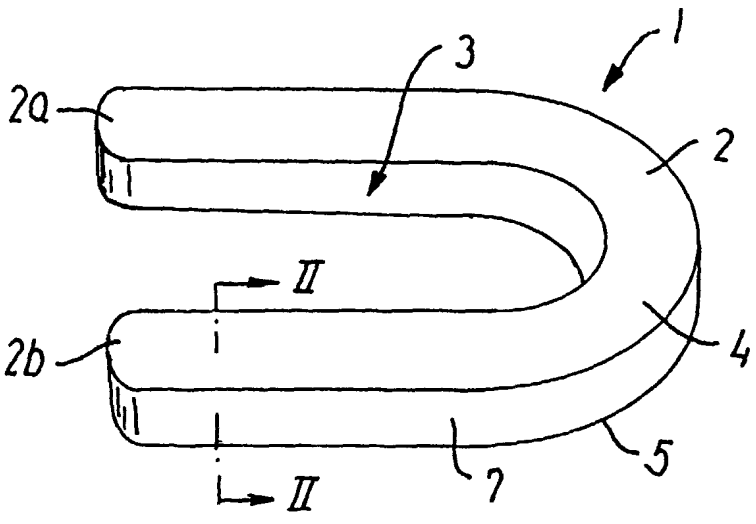
(84) Designated States *(regional)*: Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/068111 A1

(54) Title: IMPLANT FOR SPINE AND METHOD FOR MANUFACTURING SAME



(57) Abstract: Implant (1) for replacing an element in a vertebral or cervical spine, which implant (1) comprises a base body (2) manufactured of a substantially X-ray penetrable material, characterized in that the implant has a surface modification (9) comprising an X-ray proof material

Implant for spine and method for manufacturing same

The invention concerns an implant for replacing an element in a vertebral or cervical spine, which implant comprises a base body manufactured of a substantially X-ray penetrable material.

The stability and the function of the spine are based on the relations between spinal bodies (corpora), discs (disci intervertebrales), ligaments and musculature. Between any two spinal bodies of the spine is arranged a disc, which comprises a soft cartilaginous disc surrounded and enclosed by a fibrous ring (annulus fibrosus), which prevents the cartilaginous disc from leaving the space between the spinal bodies.

The disc can be displaced (slipped disc) or damaged, for example because of sedentary work, overloading, traffic accidents or illness, and problems with back or neck have become an everyday occurrence for many people. A slipped disc, meaning that the rear part of the annulus fibrosus has been hollowed or burst, can cause the disc to press against the spinal cord or a nerve root, which causes heavy pain or maybe paresis. In other cases, the disc has been overloaded or aged in such a way that the disc gets hard and dehydrated. In both cases, the disc shrinks and does not completely fill the space between the spinal bodies. This involves the risk of instability of the spine, reduced mobility and pain. In more severe cases it is necessary to remove one or more of these discs in an operation and replace them by implants.

Correspondingly, a spinal body can be damaged, for example by lateral displacement, torsion or axial compression, caused by a fall, a header in too low water or a traffic accident. Finally, spinal bodies can be damaged by illness, for example cancer. Common for these cases is that it may be necessary to remove a damaged spinal body and replace it by an implant.

During an operation, where one or more elements are removed, muscular and connective tissue is intersected, and it is necessary to make sure that the implant is fixed to neighbouring spinal elements as fast as possible, to ensure stability of the spine. For example, this fixation occurs in that bone from the two neighbouring spinal bodies grows onto the implant. It is important to be able to establish, whether or not a suitable ingrowth of bone onto the implant has taken place, and thus, whether the stability of the spine is ensured. With a traditional implant, which is made of a metal, it may be difficult to establish, whether an ingrowth has taken place, as metal is X-ray proof, which means that it creates shadows in the X-ray picture. Therefore, traditional implants made of metal are not optimal in connection with implants for the spine, as it is difficult or even impossible to determine, whether or not an ingrowth has taken place. An attempt to remedy this appears from EP 1 088 533 A1, which describes an implant as mentioned above, which consists of a basket-like container, which is made of interwoven threads or threads of metal, openings being formed between the threads, which permit X-rays to penetrate. However, this implant is very expensive in production, and besides, it is difficult to obtain a sufficient compression strength with this basket-like implant.

As appears from US patent No. 5,425,772, an implant made of, for example, polymer, maybe reinforced with fibres, can be used instead, as such an implant is X-ray penetrable, and therefore creates no shadows in an X-ray picture. However, this implant has the disadvantage that it cannot be seen from an X-ray picture, if the implant is correctly placed.

Besides, from the US patent No. 6,146,422 is known a disc implant, which is made of an X-ray penetrable material, such as a polymer, with two punctiform metal markers, which can be seen on an X-ray picture. With this embodiment, it is to some degree possible to determine the placing of the implant. It is difficult, however, to establish whether the bone grows close to the implant.

It is a purpose of the present invention to provide an implant, which enables both determination of the placing of the implant and of the bone growth around and onto the implant.

With this purpose, the implant according to the invention is characterised in that the implant has a surface modification comprising an X-ray proof material, which ensures that an X-ray will show, whether the implant is correctly placed. As the bone can be seen clearly on an X-ray picture, whether the bone grows around the implant and onto the surface, which can now be seen on an X-ray picture.

Of course, the simplest method is to modify the surface of the whole implant, but it is preferred that the surface modification merely comprises selected areas of the im-

plant, preferable only surfaces facing each other, so that both areas with surface modification and areas without surface modification exist. The areas without surface modification form some kind of "windows", which are X-ray penetrable and leave no shadows on an X-ray picture. This makes it easier to see, whether the modified surface areas are placed as desired and whether a growth of the bone has taken place around and onto the implant.

The surface modification can be any X-ray proof material, but according to an embodiment the surface modification is a refractory metal, which is X-ray proof and generally very resistant to corrosion.

It is particularly preferred that the surface modification is made of tantalum, which is X-ray proof and has appropriate, biocompatible properties, which ensure that the implant is accepted by the body and that bone can grow onto the implant itself.

In an embodiment, the surface modification is placed on at least a share of the top side and/or the bottom side of the base body, so that these surfaces appear clearly on the X-ray picture, and it can be determined, whether the implant is placed correctly and close to the neighbouring spinal bodies.

In an embodiment, the base body encloses, completely or partly, a through hollow, which extends from the top side to the bottom side of the base body. This through hollow is well suited for ingrowth of bone, thus ensuring to a higher extent a fixing of the implant in the spine, which improves the stability of the spine.

It may be advantageous that the surface modification is placed on at least a share of the hollow sidewall, as thus it can be established, if the bone grows close around the implant through the hollow and maybe grows onto the surface.

According to an embodiment, the implant is characterised in that it comprises at least one net, suspended across the hollow of the base body. This creates some kind of shelf, on which a bone-growth supporting material can be placed. A further advantage of this net is that ingrowth into the net will prevent a relative displacement of the implant in relation to the neighbouring spinal bodies.

In many cases, one single net will be sufficient and suitable, but in some cases it may be appropriate that the implant comprises two nets, suspended at a certain distance from each other across the hollow, substantially in parallel with the top side and/or the bottom side of the base body. With this implant, a pocket has been created, in which bone-growth material can be placed, meaning that the bone-growth material is better secured against falling off, and at the same time it improves the chances of a fast ingrowth of bone into a net, so that an early protection against displacement of the implant is achieved.

Further, it may be appropriate that the surface modification is placed on the net, so that it is covered with an X-ray proof material, or that the net is made of threads of an X-ray proof material, like tantalum or platinum, as this will make the net appear clearly on an X-ray picture,

which makes it easy to see, if an ingrowth of bone into the net has taken place.

One embodiment is characterised in that the base body has substantially the shape of a horseshoe with two branches. This embodiment has turned out to be particularly appropriate for an implant meant for replacing an element in the spine.

An implant, whose base body has the shape of a closed ring with a circular, oval or polygonal basic shape has proved to be well suited for insertion in the cervical spine, among other things because here the dimensions of the elements are relatively small.

Fixation in the period, until ingrowth has taken place, can, among other things, be achieved by a so-called Harrington-system, which consists of long bars inserted around the spine with the purpose of fixing it, but such systems are inconvenient for the patient, and often there is a risk that the bars work loose. In order to achieve a better fixation, the implant is, in one embodiment, provided with diagonal, through holes from an outside of the base body to the top side and/or the bottom side of the base body, respectively, meaning that the implant can be fixed by means of screws or brads to one or both of the neighbouring spinal bodies. This is particularly important during the period, where ingrowth of bone into the implant has not yet taken place.

The invention also concerns a method for manufacturing an implant for replacement of a disc in a spine.

In the following, the invention will be described in detail on the basis of an embodiment example and with reference to the enclosed drawings, showing:

Fig. 1 an implant according to the invention having the shape of a horseshoe,

Fig. 2 a cross-section II-II in Fig. 1

Fig. 3 an implant according to the invention having the shape of a ring

Fig. 4 a cross-section in Fig. 3

Fig. 5 a section through an implant provided with spikes,

Fig. 6 an implant provided with a net,

Fig. 7 a section VII-VII in Fig. 6

Fig. 8 a ring-shaped implant provided with a net

Fig. 9 a cross-section in Fig. 8

From Fig. 1, which schematically shows an implant 1 according to the invention, it appears that the implant 1 comprises a horse-shoe shaped base body 2 with two branches 2a, 2b, which partly enclose a through hollow 3, extending from a top side 4 of the base body 2 to a bottom side 5 of the base body 2.

After the implantation of an implant it is essential to be able to determine, whether the implant is placed correctly, and whether an ingrowth of bone into and towards the implant takes place to ensure that the implant is safely fixed on the neighbouring bones. It is therefore preferred that the implant is visible on an X-ray picture, but at the same time it is particularly preferred that the implant does not create shadows on the X-ray picture, which will make it difficult or impossible to determine, whether or not an ingrowth into the hollow 3 of the implant has taken place. As appears from Fig. 2, the implant 1 can have a complete or partial surface modification 9, which is completely or partly X-ray proof. Particularly in connection with a base body 2, which is made of an X-ray penetrable material, this has the advantage that the surface of the implant is clearly visible on an X-ray picture, and it is therefore easy to determine, whether a bone ingrowth into the implant has taken place. The surface modification can be any X-ray proof material suited for implantation into a living organism, meaning that it is preferred that the material is biocompatible. Examples of suitable materials are refractory metals, such as niobium and tantalum, as well as the metal titanium. It can be mentioned that a surface modification 9 of tantalum with a thickness of 5 to 10 μm will provide the desired X-ray proofness, and at the same time there will be no disturbing shadows on the X-ray picture, as a surface modification with this thickness will still be X-ray penetrable to some extent.

An implant 1 of this type, comprising a base body 2 with horse-shoe shape has turned out to be particularly well suited for replacement of an element in a vertebral spine,

whereas in connection with implants for replacement of elements in the cervical spine it is usually preferred that the implant 1 as shown in Fig. 3 comprises a base body 2 in the shape of a closed ring, which can, for example, be circular or rectangular, said base body 2 enclosing a through hollow 3.

The surface modification can cover the whole implant or, as shown in Fig. 4, only a limited share, such as facing parts of side faces of the base body inside the hollow. Thus, it can be achieved that some kind of X-ray penetrable "windows" are formed in the areas having no surface modification, so that an X-ray picture makes it possible to determine, whether ingrowth of bone through the hollow of the implant and towards the surface of the implant has taken place, as the surface modified areas will be visible on the X-ray picture.

The base body 2 can have through holes (not shown) from a side face 7 to the top side 4 and/or the bottom side 5, respectively, of the base body 2. These holes permit the insertion of brads, screws or the like for fixing the implant in relation to the neighbouring spinal bodies.

Thus, it is obtained that the implant 1 cannot be displaced during the period, where an ingrowth of bone material through the implant has not yet taken place. However, it must be mentioned that in connection with implants for replacement of an element in the cervical spine it will often not be possible to fix the implant to the neighbouring spinal bodies by means of screws or brads, as the spinal bodies of the cervical spine are relatively small. Additionally to this, or instead of this, the top side and

or the bottom side 4, 5 of the base body 2 can be rugged, or, as appears from Fig. 5, be provided with relatively pointed spikes or combs 8, which expediently extend in different directions. This minimises the risk that the implant is displaced in relation to the neighbouring spinal bodies.

At the top side 4, the bottom side 5, or somewhere between the top side 4 and the bottom side 5, a net 6 can be suspended, as shown in Figs. 6, 7, 8 and 9, which net 6 is substantially parallel to the top side 4 and/or the bottom side 5. This net can be provided with a layer of bone-growth supporting material, such as the product Colloss® from the German company Ossacur AG.

As shown in Figs. 8 and 9, the implant 1 can comprise one single net 6, or, as shown in Fig. 7, which is a section VII-VII in Fig. 6, the implant 1 can advantageously comprise two nets 6a, 6b, which are suspended between the two branches 2a, 2b of the base body 2. This will advantageously form a pocket 10, in which bone-growth supporting material can be placed.

The base body 2 of the implant 1 can be made of a fibre-reinforced polymer, in which the fibres are further used for creating the net 6. In this way, the net 6 can expediently be produced integrally with the base body 2. Alternatively, the net 6 can be mounted on the base body 2. Examples of suited polymers are PEEK (polyetheretherketone) and PEKEKK, and the fibres can, for example, be carbon fibres.

The implant can also be made of graphite, carbon fibre-reinforced graphite or metal. In this case, the base body can be made of metal in bulk, extruded, maybe with a net, or sintered powder or foamed material.

Suited dimensions of an implant for replacement of a disc in the vertebral spine of an adult will be a height of about 10 to 13 mm, a width of about 8 mm and an opening, whose largest dimension is about 25 mm. An implant for a child will of course be somewhat smaller.

Suited dimensions of an implant for replacement of a disc in the cervical spine of an adult will be a height of about 8 mm, a width of about 20 mm and a depth of about 10 mm. The hollow can, for example, have a cross section of about 4 times 12 mm.

In case that the implant must replace a spinal body, it will be obvious for a person skilled in the art that the implant must be substantially higher.

The figures show implants with parallel top and bottom sides, but in some cases it may be appropriate for the implant to be wedge-shaped, so that the heights of the front and the rear sides of the implant are different, which will give the desired curvature of the spine.

Patent Claims

1. Implant (1) for replacing an element in a vertebral or cervical spine, which implant (1) comprises a base body (2) manufactured of a substantially X-ray penetrable material, characterised in that the implant has a surface modification (9) comprising an X-ray proof material.

2. Implant (1) according to claim 1, characterised in that the surface modification (9) merely comprises selected areas of the implant (1), preferable only surfaces opposite each other.

3. Implant (1) according to any of the preceding claims, characterised in that the surface modification (9) is a refractory metal.

4. Implant (1) according to claim 3, characterised in that the surface modification (9) is made of tantalum.

5. Implant (1) according to claim 3, characterised in that the surface modification (9) is placed on at least a share of the top side (4) and/or the bottom side (5) of the base body (2).

6. Implant (1) according to any of the preceding claims, characterised in that the base body (2) encloses, completely or partly, a through hollow (3), which ex-

tends from the top side (4) to the bottom side (5) of the base body (2).

7. Implant (1) according to claim 6, characterised in that the surface modification (9) is placed on at least a share of the hollow (3) sidewall.

8. Implant (1) according to claim 6 or 7, characterised in that the implant (1) comprises at least one net (6), suspended across the hollow (3).

9. Implant (1) according to claim 8, characterised in that the surface modification (9) is placed on the net (6), or that the net (6) is made of threads of an X-ray proof material, like tantalum or platinum.

10. Implant (1) according to any of the preceding claims, characterised in that the base body (2) has the shape of a horseshoe with two branches (2a, 2b).

11. Implant (1) according to any of the preceding claims, characterised in that the base body (2) has the shape of a closed ring with a circular, oval or polygonal basic shape.

12. Implant (1) according to any of the preceding claims, characterised in that the implant (1) is provided with diagonal, through holes from an outside (7) of the base body (2) to the top side and/or the bottom side (4, 5) of the base body (2).

13. Method of manufacturing an implant (1) for replacing an element in a spine, which implant (1) comprises a

base body (2) manufactured of a substantially X-ray penetrable material, characterised in that the base body (2) is surface modified to form a surface modification (9) of an X-ray proof material.

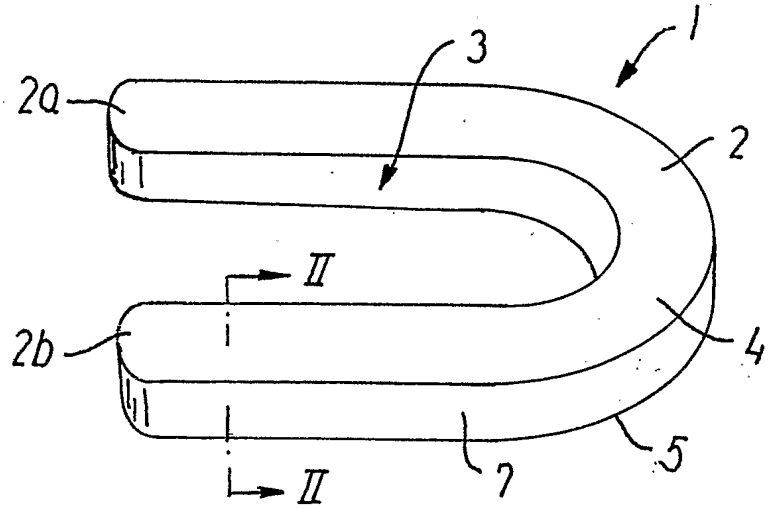


FIG.1

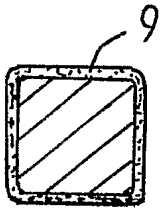


FIG.2

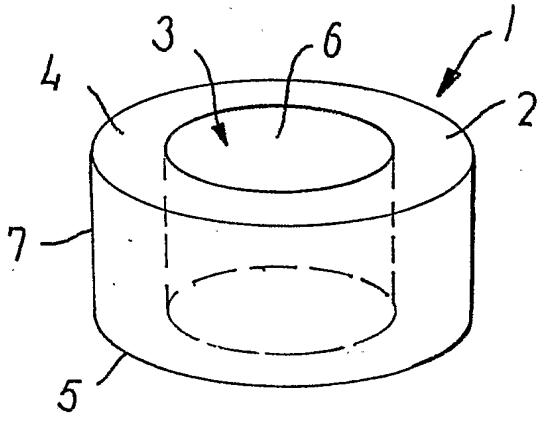


FIG.3

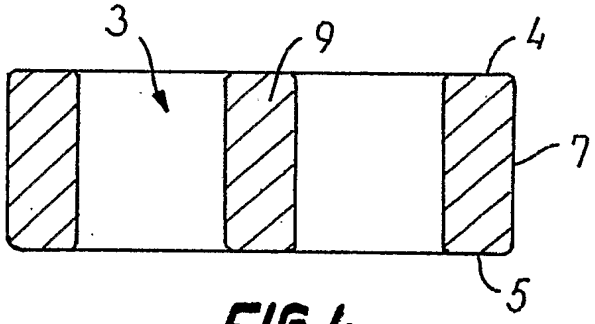


FIG.4

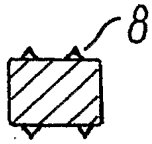


FIG.5

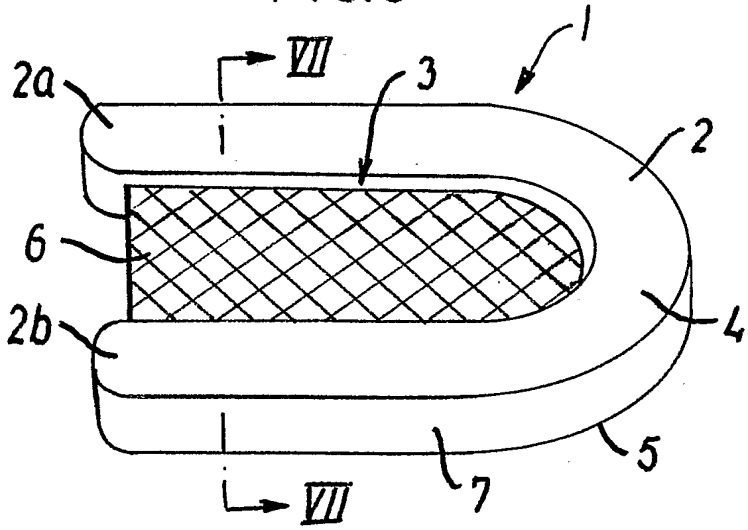


FIG.6

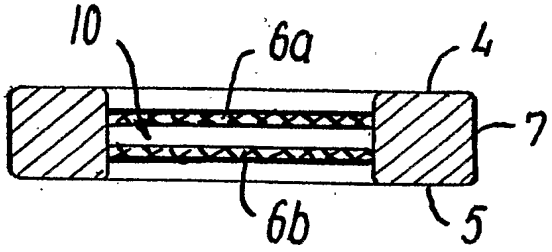


FIG.7

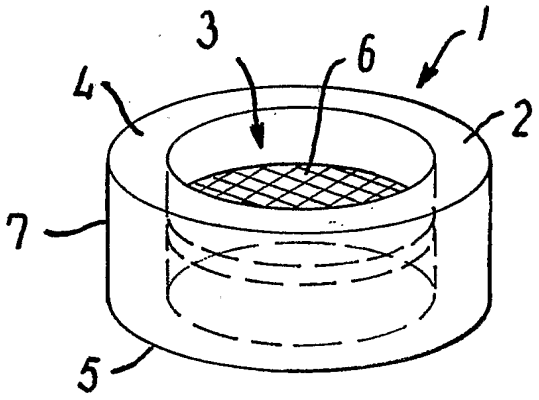


FIG.8

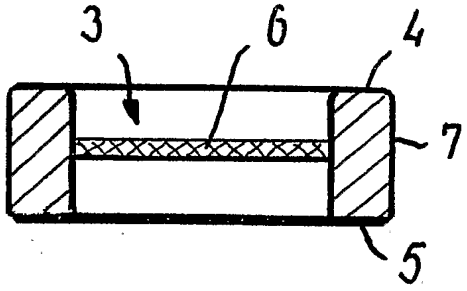


FIG.9

INTERNATIONAL SEARCH REPORT

Internatio[illegible]plication No
PCT/DK 03/00081

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 088 533 A (SULZER ORTHOPEDICS LTD) 4 April 2001 (2001-04-04) figure 1 abstract ---	1-3,6-9, 11,13
X	WO 01 15637 A (SCHAER MANUEL ;BERNHARD JEROME (CH); SYNTHES AG (CH); TAGWERKER KO) 8 March 2001 (2001-03-08) page 5, line 19 -page 7, line 12; figure 1 ---	1-7,10, 12,13
A	EP 0 560 279 A (ULTRAMET) 15 September 1993 (1993-09-15) abstract ---	1-13
A	US 5 782 919 A (RAY III EDDIE ET AL) 21 July 1998 (1998-07-21) column 5, line 24 - line 32 -----	1-13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 April 2003	27 05 2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	LEIF BRANDER / ELY

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/DK 03/00081

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1088533 A	04-04-2001	EP 1088533 A1	04-04-2001
		US 6447543 B1	10-09-2002
WO 0115637 A	08-03-2001	WO 0115637 A1	08-03-2001
		AU 754038 B2	31-10-2002
		AU 5856299 A	26-03-2001
		EP 1207821 A1	29-05-2002
		JP 2003508119 T	04-03-2003
EP 0560279 A	15-09-1993	US 5282861 A	01-02-1994
		DE 69328843 D1	20-07-2000
		DE 69328843 T2	02-11-2000
		EP 0560279 A1	15-09-1993
		ES 2148191 T3	16-10-2000
		JP 7255832 A	09-10-1995
US 5782919 A	21-07-1998	US 5984967 A	16-11-1999
		AT 212818 T	15-02-2002
		AU 2132897 A	10-09-1997
		AU 4733899 A	11-11-1999
		AU 705991 B2	03-06-1999
		AU 4829296 A	10-10-1996
		AU 705930 B2	03-06-1999
		AU 4829496 A	10-10-1996
		CA 2171907 A1	28-09-1996
		CA 2171921 A1	28-09-1996
		CN 1143488 A	26-02-1997
		CN 1143489 A	26-02-1997
		DE 69619007 D1	21-03-2002
		DE 69619007 T2	29-08-2002
		EP 1147751 A2	24-10-2001
		EP 0734703 A2	02-10-1996
		EP 0888099 A2	07-01-1999
		ES 2172635 T3	01-10-2002
		JP 8266565 A	15-10-1996
		JP 8294495 A	12-11-1996
		NO 961213 A	30-09-1996
		NO 961214 A	30-09-1996
		TR 960950 A2	21-11-1996
		TR 960951 A2	21-11-1996
		US 6206922 B1	27-03-2001
		WO 9731517 A2	28-08-1997
		US 2002193802 A1	19-12-2002
		US 6245072 B1	12-06-2001
		US 5669909 A	23-09-1997
		US 6375655 B1	23-04-2002
		US 2002022845 A1	21-02-2002
		US 2001005796 A1	28-06-2001
		ZA 9602368 A	01-10-1996
		JP 2001508319 T	26-06-2001